

## REMARKS

### The Office Action

Applicants gratefully acknowledge the thoughtful and detailed Office Action mailed July 30, 2007. The amendments to the claims presented above are thought by the Applicants to be fully responsive to each ground of rejection put forth by the Examiner. Therefore, Applicants request reexamination and allowance of all pending claims in view of the submitted amendments and the comments presented below.

To summarize the Office Action:

1. The Examiner objected to informalities in claims 32, 34-36, 38, and 40-42 arising from the use of the words "image studies" in the claims. The amendments presented above remove these words from these claims.
2. Claims 2, 4, 16, 19, 20, and 31 were rejected under 35 U.S.C. 112, first paragraph, as containing subject matter not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, were in possession of the invention. Comments regarding these claims below address this ground of rejection.
3. Claims 1, 18-19, 34, 36, and 40-44 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to point out particularly and distinctly claim the subject matter that the applicants regard as the invention. Specifically, one or more terms in each of these claims were cited as failing to have an antecedent basis. Applicants submit that the amendments presented above address the antecedent basis issues presented in the Office Action.
4. Claims 1-44 were rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to point out and distinctly claim the subject matter that applicants regard as their invention because the claims use vague and indefinite terms. Applicants

submit that the amendments presented above in light of the remarks made below remove this ground of rejection.

5. Claims 1-17 and 32-27 were rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential elements, because the omissions amounted to gaps between the elements. Applicants submit that the claims as amended do not omit essential elements and that this ground of rejection has been overcome.

6. Claims 18-31 and 38-44 were rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, because the omissions amounted to gaps in the processing. Applicants submit that the claims as amended do not omit essential processing performed by the method and that this ground of rejection has been overcome.

7. Claims 1-44 were rejected under 35 U.S.C. 101 as being directed to non-statutory subject matter because the claimed system did not produce any useful, tangible, and concrete results. The Examiner also noted that the elements of the system were software only and, therefore, not statutory. Applicants have amended the claims to include the computers on which the programs execute to form a computer system. This description of Applicants' invention is set forth on page 18, lines 1-14. Applicants, therefore, submit that the computer system operating under the control of the elements set forth in claims 1-17 and 32-37 constitute patentable subject matter. In a similar manner, claims 18-31 and 38-44 have been amended to identify the process as a method of operating a computer to achieve the concrete result of generating and storing a set of artificial implant model data in a database that are later retrieved and used to fabricate an artificial implant.

8. Claims 18-33 and 38-39 were rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent Number 6,205,411 to DiGioia, III et al. (hereinafter "DiGioia"). In light of the amendments made above, Applicants submit that these claims require generation of a set of artificial implant data that corresponds to an artificial

implant operating within a set of dimensional range values obtained from joint motion image data for a plurality of joints in a plurality of subjects. These limitations are not disclosed by DiGioia or any other reference of record.

Each ground of rejection is now addressed.

### Objections

Objection was made to claims 32, 34-36, 38, and 40-42 because these terms included the term “image studies.” These claims have been amended to remove this term.

Consequently, the objections made in the Office Action have been overcome.

### 35 U.S.C. 112, First Paragraph Ground of Rejection

Claims 2, 16, 19, and 21

With regard to these claims, the Examiner required a reference to the specification for the purpose of identifying a method of computing differential data. In response to this direction, Applicants begin by directing the Examiner’s attention to page 9, lines 1-7. There the anthropometric data is described as providing dimensional measurements. Dimensional measurements would be understood by one of ordinary skill in the art as being distance measurements. These dimension measurements and the ranges obtained from a set of the anthropometric image data are used to generate artificial implant model data. Thus, one of ordinary skill in the art would understand that the model data are also related to distance measurements for physical dimensions of the artificial implant that corresponds to the artificial implant model data. Page 9, lines 10-13 indicates that the joint motion image data, such as fluoroscopic images, include positional data. These positional data are related to the motion versus time data as page 10, lines 19-22 describes the joint motion image data as possessing motion versus time data. This correlation is reasonable as motion versus time data relate to positions at particular times. Thus, one of ordinary skill in the art would understand differential dimensional data as being a difference between two positions or two measurements of a dimension.

Consequently, these differences when used by the artificial implant model data generator to generate another set of artificial implant model data modifies the dimensions of a previous artificial implant model by subtracting or adding the differences obtained by comparing the motion versus time data generated by the simulated movement of the joint and the joint motion image data for a plurality of joints in a plurality of subjects. The descriptions of the dimension measurements, positional data, and motion versus time data sufficiently describe the spatial refinement of the artificial implant corresponding to the set of artificial implant model data that are generated and modified by the claimed system. Therefore, Applicants submit that the generation of the differential dimension data recited in claims 2, 16, 19, and 31 is adequately described in the specification to one of ordinary skill in the art.

#### Claims 4 and 20

This ground of rejection was relied upon with reference to claims 4 and 20 because the Examiner stated that the term “acceptance parameter” was not adequately described anywhere. While Applicants believe differently, the term has been removed from these claims to facilitate the reexamination of the claims. Thus, this ground of rejection has been overcome with respect to these two claims.

#### 35 U.S.C. 112, Second Paragraph Ground of Rejection

#### TERMS WITHOUT ANTECEDENT BASIS

##### Claims 1 and 18

Claims 1 and 18 were rejected for having the term “the dynamic response” in the claims with no antecedent basis. These claims have been amended to remove this term and, therefore, this ground of rejection has been overcome.

##### Claims 19 and 44

Claims 19 and 44 were rejected for having the term “the kinematic model” in the claims with no antecedent basis. These claims have been amended to remove this term and to

provide other terms with proper antecedent basis. Therefore, this ground of rejection has been overcome.

Claims 34, 36, 40, and 44

Claims 34, 36, 40, and 44 were rejected for having the term “the joint motion image studies” in the claims with no antecedent basis. These claims have been amended to remove this term and, therefore, this ground of rejection has been overcome.

Claims 34 and 40

Claims 34 and 40 were rejected for having the term “the degree of motion” in the claims with no antecedent basis. These claims have been amended to remove this term and, therefore, this ground of rejection has been overcome.

Claims 36 and 42

Claims 36 and 42 were rejected for having the term “the motion versus time response data” in the claims with no antecedent basis. These claims have been amended to remove this term and, therefore, this ground of rejection has been overcome.

Claim 41

Claim 41 was rejected for having the term “the analysis of anthropometric data” in the claim with no antecedent basis. This claim has been amended to remove this term and, therefore, this ground of rejection has been overcome.

Claims 42 and 43

Claims 42 and 43 were rejected for having the term “the analysis of joint motion data” or the term “the joint motion data” in the claims with no antecedent basis. These claims have been amended to remove these terms or provide an adequate antecedent basis. Therefore, Applicants submit that this ground of rejection has been overcome.

## CLAIMS BEING VAGUE AND INDEFINITE

All of the pending claims were rejected as including one or more terms that the Examiner asserted were vague and indefinite or as depending from a claim that included such as term. The remedy for each of the cited terms or phrases is identified below.

**1. “the set of model data may be evaluated”**

This phrase has been removed from all of the pending claims.

**2. “dynamic response data” and “the dynamic response”**

This phrase has been removed from all of the pending claims with the exception of “dynamic response data analyzer,” which the Applicants submits is used in a manner that is consistent with its description in the specification.

**3. “conditional parameter”**

This phrase has been removed from all of the pending claims.

**4. “the set of model data being stored for later use in fabricating an implant that corresponds to the set of model data”**

The Examiner indicated this phrase was vague because it was unclear whether all sets of model data were stored or only the set of model data that generates dynamic response data that meets an acceptance parameter was stored. The claims have been amended to make definite the storing of only one set of artificial implant model data that meets a specified condition.

**5. “sets that are correlated by the degree of motion”**

The phrase “degree of motion” has been replaced with “range of motion.” The Examiner did not previously reject any claims for being indefinite because “range of motion” was used. Range of motion as used in the claims refers to a range of motion for joints depicted in joint motion image data or a range of motion for a particular activity depicted

in joint motion image data. Therefore, the Applicants submit that this ground of rejection based on this phrase has been overcome.

**6. "the set of model data may be evaluated"**

The Examiner rejected claims containing the phrase "may be evaluated" because it did not state data was being evaluated. The phrase "may be evaluated" has been removed from all of the pending claims.

**7. "studies"**

This word has been removed from all of the pending claims.

**SYSTEM CLAIMS LACKING ESSENTIAL ELEMENTS**

The system claims 1-17 and 32-27 were rejected under 35 U.S.C. 112, second paragraph for omitting essential elements. Applicants submit that the claims have been carefully reviewed and amended to couple all of the elements to one another to generate and store a set of artificial implant model data for the fabrication of an artificial implant that provides the range of motion for joints depicted in joint motion image data or for an activity depicted in joint motion image data. Therefore, Applicants submit these claims include all essential elements and are ready for reexamination. Also, as noted previously, many of the gaps observed by the Examiner deal with terms or phrases that are no longer used in the claims. For at least these reasons, Applicants submit that the system claims 1-17 and 32-27 are in condition for reexamination and allowance.

**METHOD CLAIMS HAVING PROCESSING GAPS**

The method claims 18-31 and 38-44 were rejected under 35 U.S.C. 112, second paragraph for having gaps in the processing set forth in these claims. Applicants submit that the claims have been carefully reviewed and amended to couple all of the image processing to one another to generate and store a set of artificial implant model data for the fabrication of an artificial implant that provides the range of motion for joints depicted in joint motion image data or for an activity depicted in joint motion image data.

Therefore, Applicants submit these claims are ready for reexamination and allowance. Also, as noted previously, many of the gaps observed by the Examiner deal with terms or phrases that are no longer used in the claims. For at least these reasons, Applicants submit that all of the pending method claims are in condition for allowance.

### Section 101 Ground of Rejection

The Examiner has rejected claims 1-44 as failing to be directed to statutory subject matter because they are directed to software. According to the Examiner the system should display some results on a display terminal or save the results in a file. Applicants have amended claim 1 and claim 32 to include computers on which the various components of the system execute. The implementations of the system as a single computer executing all of the components or as group of computers executing programs and communicating with one another are set forth in the specification at page 18, lines 1-14. Specific computers, namely, CAD systems are also described as being capable of being controlled by the execution of the computer components set forth in the claims and described in the specification. The viewing of bones and the selection of points to define dimension measurements with a CAD system is an indirect reference to a display and an input device operating under control of the system components described in the specification and set forth in the claims. Consequently, Applicants submit that the claims are not directed to software alone and therefore, constitute patentable subject matter.

The computer system set forth in the system claims also produce a tangible result that is stored in a file in the computer memory. CAD systems are known as enabling its users to model, rotate, alter, operate, and display images of a physical component and then save the images and descriptive data for the physical component that is useful for manufacture of the physical component with a computer aided manufacturing (CAM) computer. The storage of the set of artificial implant model data in a database is storage in a file. Files, such as tables and other data structures, are used to stored data in a database for later retrieval and use. Therefore, Applicants submit that the system claims produce a concrete and tangible result, namely, a set of artificial implant model data that is stored in a



database and later retrieved for fabrication of an artificial implant that provides a range of motion depicted for joints in a set of joint motion image data.

With regard to the method claims, Applicants submit that they are directed to the operation of a computer system to generate a set of artificial implant data used to fabricate an artificial implant that provides a range of motion for joints depicted in joint motion image data. The execution of computer programs to cause a computer to perform a process that stores artificial implant model data for fabricating an artificial implant that provides a range of motion that accommodates a particular segment of the patient population without having to produce custom implants for each patient is a tangible and concrete result. Therefore, Applicants submit that the pending method claims are directed to patentable subject matter.

#### Section 102 Ground of Rejection

Applicants gratefully acknowledge the indication in the Office Action that claims 1-17 and 32-27 were not anticipated by DiGioia because DiGioia does not reference a plurality of patients. Applicants also appreciate the withdrawal of the section 103 ground of rejection with regard to the system claims.

In response to the section 102 ground of rejection with regard to the method claims, Applicants have amended the claims so they include the limitation in the system claims, which was noted by the Examiner. Applicants have used the word “subjects” instead of “patients” because the joint motion image data may include persons who were not necessarily patients at the time of image capture. Use of this term is supported by the specification at page 20, lines 5-10. Because each independent method claim requires image data for a plurality of joints in a plurality of subjects, these independent claims are patentable over DiGioia, which does not teach or suggest the use of image data for a plurality of joints in multiple subjects. Consequently, the independent method claims 18 and 38 are patentable over all references of record. Likewise, the claims depending from

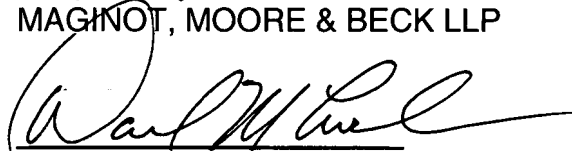
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these independent claims are also patentable over all references of record because they include this limitation.

### **Conclusion**

For the reasons set forth above, all pending claims 1-3, 5-8, 10-14, 16, 18-24, 27-28, 30-33, 37-39, and 41-43, are patentable over all references of record, either alone or in combination. Reexamination and allowance of all pending claims are earnestly solicited.

Respectfully submitted,  
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A handwritten signature in black ink, appearing to read "David M. Lockman", written over a horizontal line.

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